General Assembly

Amendment

January Session, 2019

LCO No. **11066**

Offered by:
SEN. LESSER, 9th Dist.
SEN. KELLY, 21st Dist.
REP. SCANLON, 98th Dist.

To: Senate Bill No. **4** File No. 208 Cal. No. 126

"AN ACT CONCERNING THE ACCESSIBILITY OF PRESCRIPTION DRUGS."

After the last section, add the following and renumber sections and internal references accordingly:

"Sec. 501. (NEW) (*Effective July 1, 2019*) For the purposes of this section and sections 502 to 508, inclusive, of this act, unless the context otherwise requires:

(1) "Canadian supplier" means a manufacturer or wholesale drug distributor that is licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs;

(2) "Drug" means an article that is (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement thereto, (B) intended for use in the diagnosis, cure, mitigation,

treatment or prevention of disease in humans, (C) not food and intended to affect the structure or any function of the human body, and (D) not a device and intended for use as a component of any article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

(3) "Drug Quality and Security Act" means the federal Drug Quality and Security Act, 21 USC 351, et seq., as amended from time to time;

(4) "Food, Drug and Cosmetic Act" means the federal Food, Drug and Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and Security Act, as both may be amended from time to time;

(5) "Laboratory" means an environmental laboratory as defined in section 19a-29a of the general statutes and accredited by ISO 17025;

(6) "Laboratory testing" means a quantitative and qualitative analysis of a drug consistent with the official United States Pharmacopoeia;

(7) "Participating Canadian supplier" means a Canadian supplier that is exporting prescription drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the program;

(8) "Participating wholesaler" means a wholesaler that is (A) designated by the Department of Consumer Protection to distribute prescription drugs, in the manufacturer's original container, obtained from a participating Canadian supplier, and (B) participating in the program;

(9) "Program" means the Canadian prescription drug importation program established by the Commissioner of Consumer Protection, in conjunction with the Commissioner of Public Health, pursuant to section 502 of this act;

(10) "Track-and-trace" means the product tracing process for the components of the pharmaceutical distribution supply chain as

described in Title II of the Drug Quality and Security Act; and

(11) "Wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that has received a certificate of registration from the Commissioner of Consumer Protection pursuant to said section.

Sec. 502. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of Consumer Protection, in conjunction with the Commissioner of Public Health, shall establish a program to be known as the "Canadian prescription drug importation program". Under such program, the Commissioner of Consumer Protection and the Commissioner of Public Health shall, notwithstanding any contrary provision of the general statutes, provide for the importation of safe and effective prescription drugs from Canada that have the highest potential for cost savings in this state.

(b) (1) Not later than January 1, 2021, the Commissioner of Consumer Protection shall, after consulting with the Commissioner of Public Health, submit a request to the federal Secretary of Health and Human Services seeking approval for the program under 21 USC 384(*l*), as amended from time to time. Such request shall, at a minimum:

(A) Describe the Commissioner of Consumer Protection's and Commissioner of Public Health's plans for operating the program;

(B) Demonstrate that the prescription drugs that will be imported and distributed in this state under the program will:

(i) Meet all applicable federal and state standards for safety and effectiveness; and

(ii) Comply with all federal tracing procedures; and

(C) Disclose the costs of implementing the program.

(2) (A) If the federal Secretary of Health and Human Services

approves the Commissioner of Consumer Protection's request, the Commissioner of Consumer Protection shall:

(i) Submit to the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services approved such request;

(ii) Submit to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health a notice disclosing that the federal Secretary of Health and Human Services approved such request; and

(iii) Begin operating the program in conjunction with the Commissioner of Public Health not later than one hundred eighty days after the date of such approval.

(B) Except as otherwise provided in sections 501 to 508, inclusive, of this act, the Commissioner of Consumer Protection and the Commissioner of Public Health shall not operate the program unless the federal Secretary of Health and Human Services approves the Commissioner of Consumer Protection's request.

Sec. 503. (NEW) (*Effective July 1, 2019*) Each participating wholesaler may import and distribute a prescription drug in this state from a participating Canadian supplier under the program if:

(1) Such drug meets the United States Food and Drug Administration's standards concerning drug safety, effectiveness, misbranding and adulteration;

(2) Importing such drug would not violate federal patent laws; and

(3) Such drug is not:

(A) A controlled substance, as defined in 21 USC 802, as amended from time to time;

(B) A biological product, as defined in 42 USC 262, as amended

from time to time;

(C) An infused drug;

(D) An intravenously injected drug;

(E) A drug that is inhaled during surgery; or

(F) A drug that is a parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to the public health.

Sec. 504. (NEW) (*Effective July 1, 2019*) Participating wholesalers may, subject to the provisions of sections 501 to 508, inclusive, of this act, import and distribute drugs in this state from a participating Canadian supplier under the program to:

(1) A pharmacy or institutional pharmacy, as defined in section 20-571 of the general statutes; and

(2) A laboratory registered with the Department of Public Health under section 19a-29a of the general statutes to perform analytical testing.

Sec. 505. (NEW) (*Effective July 1, 2019*) Each participating Canadian supplier and participating wholesaler shall comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this state any prescription drugs that are imported into this state under the program. Each participating wholesaler shall make available to the Commissioner of Consumer Protection all track-and-trace records not later than forty-eight hours after the Commissioner of Consumer Protection requests such records.

Sec. 506. (NEW) (*Effective July 1, 2019*) (a) The participating wholesaler shall ensure the safety and quality of all drugs that are imported and distributed in this state under the program. The participating wholesaler shall:

(1) For each initial shipment of a drug that is imported into this state by a participating wholesaler, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample size for each batch of each drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(2) For each shipment of a drug that is imported into this state by a participating wholesaler and has been sampled and tested pursuant to subdivision (1) of this subsection, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample of such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(3) Certify that each drug imported into this state under the program:

(A) Is approved for marketing in the United States and not adulterated or misbranded; and

(B) Meets all of the labeling requirements under 21 USC 352, as amended from time to time;

(4) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each drug imported into this state under the program is in compliance with the requirements of this section; and

(5) Maintain documentation demonstrating that the testing required by this section was conducted at a laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning laboratory qualifications.

(b) The participating wholesaler shall maintain all information and documentation that is submitted pursuant to this section for a period of not less than three years.

(c) Each participating wholesaler shall maintain all of the following information for each drug that such participating wholesaler imports

and distributes in this state under the program, and submit such information to the Commissioner of Consumer Protection upon request by the Commissioner of Consumer Protection:

(1) The name and quantity of the active ingredient of such drug;

(2) A description of the dosage form of such drug;

(3) The date on which such participating wholesaler received such drug;

(4) The quantity of such drug that such participating wholesaler received;

(5) The point of origin and destination of such drug;

(6) The price paid by such participating wholesaler for such drug;

(7) A report for any drug that fails laboratory testing; and

(8) Such additional information and documentation that the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, deems necessary to ensure the protection of the public health.

(d) Each participating Canadian supplier shall maintain the following information and documentation and, upon request by the Commissioner of Consumer Protection, submit such information and documentation to the Commissioner of Consumer Protection for each drug that such participating Canadian supplier exports into this state under the program:

(1) The original source of such drug, including, but not limited to:

(A) The name of the manufacturer of such drug;

(B) The date on which such drug was manufactured; and

(C) The location where such drug was manufactured;

(2) The date on which such drug was shipped;

(3) The quantity of such drug that was shipped;

(4) The quantity of each lot of such drug originally received and the source of such lot;

(5) The lot or control number and the batch number assigned to such drug by the manufacturer; and

(6) Such additional information and documentation that the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, deems necessary to ensure the protection of the public health.

Sec. 507. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of Consumer Protection shall issue a written order:

(1) Suspending importation and distribution of a drug under the program if the Commissioner of Consumer Protection discovers that such distribution or importation violates any provision of sections 501 to 508, inclusive, of this act or any other applicable state or federal law or regulation;

(2) Suspending all importation and distribution of drugs by a participating wholesaler under the program if the Commissioner of Consumer Protection discovers that the participating wholesaler has violated any provision of sections 501 to 508, inclusive, of this act or any other applicable state or federal law or regulation;

(3) Suspending all importation and distribution of drugs by a participating Canadian supplier under the program if the Commissioner of Consumer Protection discovers that the participating Canadian supplier has violated any provision of sections 501 to 508, inclusive, of this act or any other applicable state or federal law or regulation; or

(4) Requiring the recall or seizure of any drug that was imported

and distributed under the program and has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded.

(b) The Commissioner of Consumer Protection shall send a notice to each participating Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The Commissioner of Consumer Protection has issued such order, and provide the legal and factual basis for such order; and

(2) Such participating Canadian supplier or participating wholesaler may request, in writing, a hearing before the Commissioner of Consumer Protection, provided such request is received by the Commissioner of Consumer Protection not later than thirty days after the date of such notice.

(c) If a hearing is timely requested pursuant to subsection (b) of this section, the Commissioner of Consumer Protection shall, not later than thirty days after the receipt of the request, convene the hearing as a contested case in accordance with the provisions of chapter 54 of the general statutes. Not later than sixty days after the receipt of such request, the Commissioner of Consumer Protection shall issue a final decision vacating, modifying or affirming the Commissioner of Consumer Protection's order. The participating Canadian supplier or participating wholesaler aggrieved by such final decision may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 508. (NEW) (*Effective July 1, 2019*) The Commissioner of Consumer Protection may, in consultation with the Commissioner of Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 501 to 507, inclusive, of this act.

Sec. 509. (NEW) (*Effective July 1, 2019*) Not later than July 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy established under section 19a-754a of the general statutes shall submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health. Such report shall describe the operations of the program established pursuant to section 502 of this act during the fiscal year next preceding, and include all information prescribed in regulations adopted pursuant to section 508 of this act."

This act shall take effect as follows and shall amend the following sections:		
Sec. 501	*July 1, 2019*	New section
Sec. 502	*July 1, 2019*	New section
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